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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,819	03/18/2004	Rae Ellen Syverson	64095753 (27839-143)	7018

45736 7590 11/22/2010

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1611

NOTIFICATION DATE	DELIVERY MODE
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11/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary	Application No. 10/803,819	Applicant(s) SYVERSON ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9,10,12,13 and 15-60 is/are pending in the application.
- 4a) Of the above claim(s) 5,12,13 and 26-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10 and 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/8/10; 2/8/10; 4/7/10; 5/14/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of IDS dated 4-7-10 and 5-14-10; and RCE, amendment and response dated 2-8-10 is acknowledged.

Claims 1-6, 10, 12, 13 and 15-60 are pending.

Claims 7 and 8 are canceled.

Claims 5, 12, 13 and 26-60 are withdrawn as nonelected.

1. Claims 1-4, 6, 9, 10 and 15-25 have been considered for examination.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2-8-10 has been entered.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6, 9, 10 and 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert (J Applied Microbiol.) and US 5,612,045 to Syverson in view of US 3393678 to Pacini et al, US 6248343 to Jampani et al and US 4318404 to Cunningham **OR** unpatentable over Pacini et al in view of Cunningham, Lambert, US

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6248343 to Jampani et al and Syverson **OR** unpatentable over Cunningham in view of Lambert, Syverson, US 6248343 to Jampani et al and Pacini et al.

Lambert studied the minimum inhibitory concentrations of different antimicrobial compounds against *S. aureus* and observed that phenoxyethanol and phenyl ethyl alcohol (designated as PoE and PeA respectively) are effective against *S. aureus* (abstract, page 276, col. 1, table 2, page 278, col. 2 and Discussion), even though the MICs vary with the inoculum levels. Lambert does not teach phenoxyethanol on a non-absorbent article as claimed in the instant invention.

Lambert fails to teach the claimed tampon applicator that is non-absorbent.

Syverson teaches catamenial tampons for absorbing body fluids that include an effective amount of a compound that substantially inhibit the production of exoprotein produced by Gram positive bacteria, particularly produced by *S. Aureus* (abstract, col. 3, lines 40-60). The compounds of Syverson comprise ethers, which are the same as the elected sub-species of the instant claims (col. 3, lines 61-55). Syverson teaches including effective amounts of ether compounds and combinations of other antimicrobial or antibacterial compounds (col. 5).

While Syverson teaches absorbent tampons, instant claims require tampon applicator that is non-absorbent. Syverson states that the tampon may or may not have an applicator.

Pacini et al teach catamenial devices such as tampons that have antibacterial properties as well as physical lubricity (col. 1, L 8-14). Pacini teach that polymetallic pectinates can be made into films or their dispersions may be sprayed or applied to

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materials intended for vaginal tamponing. It is suggested that the compound may be applied to the textile fabric of a tampon or to the external surface of the tubular tampon applicator (col. 2, L 38-51) because menstrual discharges provide a favorable condition for bacterial or other microbial growth (col. 3, L 1-40).

Pacini does not teach the claimed non-absorbent applicator.

Cunningham describes a tampon and its applicator, where the tampon is made of absorbent material and the applicator is made of non-absorbent material (see claim 13 of Cunningham).

Jampani teaches therapeutic antimicrobial compositions comprising phenoxyethanol (example 9, col. 19, lines 1-5), wherein the compound is present in 0.1 to 1% weight, effective against a number of bacteria including *Streptococcus aureus*, *E.coli* etc (table 5).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the antibacterial phenoxyethanol of Lambert and the second active agent (ether compounds) taught by Syverson, both of which are effective against *S. aureus*, in the tampon applicators (Cunningham) because both Lambert and Syverson suggests employing compounds that for inhibiting toxic shock syndrome (caused by *S. aureus*) caused by the use of tampons, and Pacini suggests that antimicrobial compounds may be employed either in the tampon fabric itself or in the enclosure that holds tampons (tampon applicator) so as to inhibit the vaginal microbial growth during menstrual cycles.

Alternatively, Pacini does not teach the claimed compounds. However, it would have been obvious for one of an ordinary skill in the art at time of the instant invention to incorporate phenoxyethanol of Lambert and the second active agent of Syverson in the tampon or applicator of Pacini because Lambert teaches phenoxyethanol is effective against *S. aureus* and Syverson also suggests the claimed second agent for the same reason. Further a skilled artisan would have employed a non-absorbent article for the tampon applicator because Cunningham suggests non-absorbent tampon applicators. Further, optimizing the amounts of ether (of Syverson) and phenoxyethanol of Lambert, with an expectation to provide the optimum inhibitory effect of *S. aureus* toxin production would have been within the scope of a skilled artisan. With respect to the claimed amounts, a skilled artisan would have readily recognized that phenoxyethanol in amounts of 0.1% to 1% by weight would be effective against several bacteria including *S. aureus* from the teachings of Jampani. Even though Jampani fails to teach incorporating antimicrobial composition on the claimed articles or the amounts of phenoxyethanol in claimed millimole amounts, a skilled artisan would have been able to optimize the amounts of phenoxyethanol to be incorporated so as to achieve the desired inhibitory effect.

Response to Arguments

3. Applicant's arguments filed 2-8-10 have been fully considered but they are not persuasive.
4. Applicants argue that Lambert teaches a method to quantify the effect in the region between reversible and irreversible damage, or sublethal injury to cell death; and

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according to Lambert on a molar basis, phenethyl alcohol is a better inhibitor than phenoxyethanol against *S. aureus*. It is argued that as the Office recognizes on pages 2-3 of the instant final Office action, Lambert does not teach or suggest phenoxyethanol on a non-absorbent substrate and Lambert fails to teach the claimed non-absorbent tampon applicator. Further, Lambert does not teach or suggest a first active ingredient such as phenoxyethanol deposited on a non-absorbent substrate present in an amount of from about 0.5 micromoles per gram of non-absorbent substrate to about 100 micromoles per gram of non-absorbent substrate. It is argued that not all antibacterial compounds are appropriate for use in vaginal area. Applicants' arguments are not persuasive because the rejection includes the teachings of Syverson, which teaches the infections caused by *S. aureus* in vaginal area and Lambert teaches antimicrobial compounds that inhibit the same bacteria that Syverson teaches causes infection in vaginal area. The present rejection also cites Jampani, which also teaches the claimed compound against the *S. aureus*. Accordingly, a skilled artisan would be able to employ the compounds of Jampani or Lambert for inhibiting *S. aureus*.

5. KSR, 550 U.S. at ____, 82 USPQ2d at 1396. Some exemplary rationales that may support a conclusion of obviousness include: (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art.

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6. The argument that Lambert teaches biocidal effect killing beneficial bacteria is not persuasive because instant claims do not exclude killing of other bacteria.

7. Applicant argues that Syverson is directed to absorbent articles, such as catamenial tampons, which include an effective amount of an ether compound to substantially inhibit the production of exotoxins by Gram positive bacteria, specifically, the tampon contains an effective amount of the inhibiting ether compound to substantially inhibit the formation of TSST-I when the tampon is exposed to *S. aureus* bacteria. It is argued that the Office recognizes on page 3 of the instant final Office action, while Syverson only teaches absorbent tampons and states that the tampon may or may not have an applicator, the instant claims require an applicator that is non-absorbent. It is argued that instant claims require first active on the non-absorbent substrate in specified amount. However, the argument is not persuasive because instant rejection is not based on one reference and the teachings of Pacini have been referred to for catamenial devices with antimicrobial compounds and that of Cunningham for non-absorbent applicators. Thus, the cited art recognizes tampons with non-absorbent applicators, wherein the applicators as well as the tampons have antimicrobial properties.

8. The argument that the rejection lacks clear articulation is not persuasive because the rejection explained that tampons (absorbent and non-absorbent) with antibacterial properties are desired in the prior art. The rejection also provided the rationale for the combination of antibacterial (particularly against *S. aureus*) and compounds (first and second) and finally the rejection provided the teaching that phenoxyethanol is very

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effective against *S. aureus*. Thus, it is the position of the examiner that the office established the requisite articulation as required by KSR, 550 U.S. at ____, 82 USPQ2d at 1396.

9. In response to Applicants' argument that the references do not teach inhibition of exoprotein at claimed amounts, firstly it is noted that instant claims are directed to a product and the limitation "for inhibiting" is an intended use. However, the references of Lambert and Jampani recognize the compounds claimed against same bacteria. The burden is on applicants to show that the amounts taught by the above references do not inhibit the exoprotein. Applicants have not shown that incorporating phenoxyethanol and ether compounds on the non-absorbent article fails to inhibit the exoprotein. If a prima facie case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the prima facie case. See, e.g., *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990). Applicants' argument regarding polymetallic pectinates of Pacini is not persuasive because the rejection is not for including pectinates but for the teachings of antimicrobial compounds on the tampons.

10. Applicants' argument regarding rejection of the claims of any one of the combinations is not persuasive because firstly, instant rejection now removes the term "over any one of the" and further, the combination for the reasons explained above provides the motivation to arrive at the claimed composition on non-absorbent article. The rejection detailed in the preceding paragraphs provides a reasonable expectation of success in inhibiting the exoproteins of *S. aureus* by including a combination of

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antimicrobial compounds (against *S. aureus*) in the absorbent or a non-absorbent substrate of a tampon. With respect to the arguments that Lambert does not teach combination of compounds and a non-absorbent article, Pacini teaches different compounds other than the claimed compounds, Syverson teaches an absorbent substrate and Cunningham fails to disclose depositing any antimicrobial substance, In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In *KSR*, the Supreme Court stated that an invention may be found obvious if it would have been obvious to a person having ordinary skill to try a course of conduct. Further, known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art. In the instant case, the prior cited in rejecting the instant claims is not providing a general concept or requires a skilled artisan to explore a new technology and instead provides the specific teachings of inhibiting *S.aureus* with compounds that are more effective (phenoxyethanol of Lambert) than others and incorporating such compounds on non-absorbent substrates of tampons (Cunningham).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611